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Germline Editing: Two Steps Forward, One Step Back?

*Kristina M. Smith**

I. INTRODUCTION

As technology develops, the law which regulates technology must also develop. Scientists and policymakers must decide what technology to create and if our society will tolerate or approve these new creations. In particular, the emerging technology in genetic editing is becoming a double-edged sword. On one side, editing genes could revolutionize disease treatment and help many families have children free of crippling hereditary diseases. But on the other hand, gene editing could affirm certain traits as superior and lead to a “designer-baby” industry where parents order children according to preference, like a customizable product. With diverging opinions and policies supporting contradictory legal frameworks, Congress has many options. This note discusses the various legal approaches of the states to genetic editing, with a focus on germline editing. Based on this analysis, Congress is likely to remove the prohibition on public funding for germline editing research but retain its ban on clinical trials.

II. GERMLINE EDITING AND CRISPR

Genome editing involves the removal, replacement, or addition of genetic material in any cell’s DNA sequence.¹ Laboratory scientists edit DNA sequences using specific “‘scissor’ proteins that can recognize a specific piece of DNA amongst the entire genome and make a break in the double helix” at the specific location.² Scientists that edit genomes may use the DNA break to alter the DNA sequence or to allow the DNA sequence to heal incorrectly, which causes the gene it resides in to become inactive.³

There are two types of genome editing: somatic cell editing and germline cell editing.⁴ Somatic cells make up most of the body’s cells and contain nonhereditary genetic information.⁵ In contrast, germline cells make up the body’s reproductive material including eggs, sperm, and embryo cells.⁶

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1. *Genome Editing and Stem Cells: Questions and Answers*, EUROSTEMCELL, <http://www.eurostemcell.org/genome-editing-and-stem-cells-questions-and-answers> (last visited Apr. 15, 2018).

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

Germline cells contain hereditary genetic information; therefore, the cells “do transmit their DNA from generation to generation.”⁷ Both the cost of errors and the results that may be achieved through germline editing are great. The heritable nature of the genes affected makes germline editing critical to conduct accurately since any small error will be passed on genetically to each new generation.⁸ Further, germline cell editing invites an ethical debate over the safety of the process and the possibility of introducing commercialized eugenics and designer babies.⁹

The latest technology in germline editing is a process called: Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).¹⁰ Bacteria use CRISPR to detect “invasive viral genetic material.”¹¹ In 2012, scientists at the University of California at Berkeley, led by Jennifer Doudna, discovered how to use CRISPR for “targeting genes and potentially very short stretches of a cell’s genome” and to slice a simple DNA strand with high precision.¹² Then, in 2013, scientists at the Broad Institute of Harvard Medical School and Massachusetts Institute of Technology worked together to discover a specific application for CRISPR: editing animal and plant cell genomes.¹³ Both the Berkeley group and the Broad Institute group patented their discoveries, and there is an ongoing battle between the two groups of scientists over whom owns the technology.¹⁴ The United States Patent Trial and Appeal Board recently determined that the patents cover distinct inventions; therefore, both sets of patents are valid.¹⁵

7. *Genome Editing and Stem Cells: Questions and Answers*, *supra* note 1.

8. *Id.*

9. Tara R. Melillo, Note, *Gene Editing and the Rise of Designer Babies*, 50 VAND. J. TRANSNAT’L L. 757, 762 (2017). A complete discussion of the ethics of germline editing is beyond the scope of this note.

10. Joel Achenbach & Carolyn Y. Johnson, *Broad Institute Scientist Prevails in Epic Patent Fight Over CRISPR*, WASH. POST (Feb. 15, 2017), https://www.washingtonpost.com/news/science/wp/2017/02/15/broad-institute-scientist-prevails-in-epic-patent-fight-over-crispr/?utm_term=.31ad08992ec5.

11. *Id.*

12. *Id.*

13. *Id.*; Jon Cohen, *Ding, Ding, Ding! CRISPR Patent Fight Enters Next Round*, SCIENCE (July 26, 2017, 9:00 AM), <http://www.sciencemag.org/news/2017/07/ding-ding-ding-crispr-patent-fight-enters-next-round>.

14. Cohen, *supra* note 13.

15. Achenbach & Johnson, *supra* note 10. The scientists at Berkeley appealed the decision to the United States Court of Appeals for the Federal Circuit. Cohen, *supra* note 13. A more complete analysis of the patent battle is beyond the scope of this note.

The first human germline editing experiment in the world occurred in China in 2015.¹⁶ This experiment was deemed unsuccessful because the embryos experienced mosaicism.¹⁷ Scientists describe “mosaicism” as an embryo where “changes were [not] taken up [] by all of the cells.”¹⁸ After the negative results of the Chinese experiment, many organizations called for a halt on germline editing research until it could be better understood.¹⁹ The experiment vaulted germline editing onto the world stage in a negative light, one that researchers in the field have been working to shed ever since.²⁰

In July 2017, the first human germline editing experiment in the United States occurred at the Oregon Health and Science University.²¹ Although still far from clinical trials, the experiment was deemed a success because it significantly minimized the flaws of the Chinese experiment.²² Shoukhrat Mitalipov from the Oregon Health and Science University led the effort to edit the germline of multiple single-cell embryos using CRISPR.²³ The researchers created the embryos by “fertiliz[ing] eggs with the sperm of a man who has [a] mutation that causes the heart condition.”²⁴ Researchers did not intend for the experiment to result in reproduction, so the embryos only existed a few days.²⁵ Some experts in the United States, like Jennifer Doudna,²⁶ view the American experiment as encouragement for further research and for possible, future clinical trials.²⁷ The American experiment was a huge step

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16. Ariana Eunjung Cha, *First Human Embryo Editing Experiment in U.S. ‘Corrects’ Gene for Heart Condition*, WASH. POST (Aug 2, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/08/02/first-human-embryo-editing-experiment-in-u-s-corrects-gene-for-heart-condition/?utm_term=.aca682f23f58.
 17. Steve Connor, *First Human Embryos Edited in U.S.*, MIT TECH. REV. (July 26, 2017), <https://www.technologyreview.com/s/608350/first-human-embryos-edited-in-us/>.
 18. *Id.*
 19. Britt E. Erickson, *Editing of Human Embryo Genes Raises Ethics Questions*, CHEM. & ENG’G NEWS, June 29, 2015, at 20–21, <https://cen.acs.org/articles/93/i26/Editing-Human-Embryo-Genes-Raises.html>.
 20. *Id.*
 21. Connor, *supra* note 17.
 22. The American experiment showed significantly less mosaicism in the cells. *Id.*
 23. *Id.*
 24. Alessandra Potenza, *Human Embryos Edited for First Time in U.S. Using CRISPR*, VERGE (Aug. 2, 2017, 1:59 PM), <https://www.theverge.com/2017/7/27/16049340/human-embryos-dna-crispr-gene-editing-us>.
 25. Connor, *supra* note 17.
 26. Doudna discovered CRISPR use for slicing DNA at the University of California at Berkeley. Achenbach & Johnson, *supra* note 10.
 27. Potenza, *supra* note 24.

toward remedying the bad image projected from the 2015 Chinese experiment. Germline editing is primed for its resurgence on the world stage, so now is the time that legislation must change this resurgence.

III. LEGAL BACKGROUND IN THE UNITED STATES

The Dickey-Wicker Amendment, passed in 1996, prohibits the Department of Health and Human Services from funding research on human embryos.²⁸ The relevant provision of the statute bans researchers from using public funds to create an embryo solely for research purposes or for any research that subjects an embryo to risk of injury or death.²⁹ Congress attaches the Dickey-Wicker Amendment to the Departments of Health and Human Services, Labor, and Education Appropriations Bill every year.³⁰

In 2001, the Senate introduced an amendment to the Bipartisan Patient Protection Bill.³¹ The amendment attempted to ban germline modification outright,³² but the amendment was withdrawn the next day, despite having a simple majority vote in its favor.³³ In the legislative record, Senator Brownback, who proposed the amendment, withdrew it to “tighten up the language” of the amendment for more votes and planned to reintroduce the amendment again before germline editing research began in the United States.³⁴

Shortly after the first experiment in China in 2015, the National Institute of Health (NIH) voluntarily abstained from clinical trials for germline editing; it will continue the moratorium until more is known about the risks.³⁵ Also concerned about risks, Congress added an amendment to the Consolidated Appropriations Act for 2016, prohibiting the Food and Drug Administration (FDA) from accepting applications for “research in which a human embryo is intentionally created or modified to include a heritable genetic modification.”³⁶ Many scholars, like Glenn Cohen³⁷ and Eli Adashi,³⁸ believe Congress included the FDA amendment in the Appropriations Act because

28. Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, 110 Stat. 26 (1996).

29. *Id.*

30. Eileen M. Kane, *Human Genome Editing: An Evolving Regulatory Climate*, 57 JURIMETRICS J. 301, 313 (2017).

31. 147 CONG. REC. S7011, 7066–68 (daily ed. June 28, 2001) (statement of Sen. Brownback), *available at* <https://www.congress.gov/crec/2001/06/28/CREC-2001-06-28-pt1-PgS7011-7.pdf>.

32. *Id.*

33. 147 CONG. REC. S7131 (daily ed. June 29, 2001) (statement of Sen. Brownback).

34. *Id.*

35. Erickson, *supra* note 19.

36. Consolidated Appropriations Act, Pub. L. No. 114–113, 129 Stat. 2242, 2283 (2015).

there has not been enough support in recent years to pass a specific germline editing bill.³⁹ Further, the FDA amendment received additional protection as a part of an appropriations bill, which was important to government function; therefore, Congress and the president were less likely to object to a small piece of the omnibus bill.⁴⁰ Congress again attached the FDA amendment to the Consolidated Appropriations Act for 2017.⁴¹

The 2017 appropriations bill also included an amendment that required the Office of the Director of National Intelligence to formulate a plan to “monitor advances in life sciences and biotechnology that addresses . . . [United States] competitiveness in the global bio-economy and the risks and threats in genetic editing technologies,” such as CRISPR.⁴² In July 2017, the House of Representatives Committee on Appropriations submitted its annual report, which covers FDA funding.⁴³ The report acknowledged that germline editing could benefit the country but determined that “researchers do not yet fully understand all the possible side effects of editing the genes of a human embryo.”⁴⁴ But, Congress must make the decision every year whether to allow federal funding for germline research, since appropriations bills occur annually.⁴⁵ Therefore, technological advancements and changes in policy may influence Congress toward the deregulation of germline research.

In February 2017, the National Academy of Sciences released a consensus report from its international summit with China and the United Kingdom in December 2015.⁴⁶ The summit discussed germline editing and formulated an international policy stance.⁴⁷ Despite disagreement over where to draw the line, all parties agreed that ethical issues should weigh heavily and the inter-

37. Cohen is a Professor of Law at Harvard Law School and Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics. See I. Glenn Cohen & Eli Y. Adashi, *FDA is Prohibited from Going Germline*, SCI., Aug. 5, 2016, at 545.

38. Adashi is a Professor of Medical Science at Brown University. *Id.*

39. *Id.*

40. *Id.*

41. Consolidated Appropriations Act, Pub. L. No. 115-31, 131 Stat. 135, 173 (2017).

42. *Id.* § 606.

43. H.R. REP. NO. 115-232, at 68 (2017).

44. *Id.*

45. *Glossary Term — Appropriation*, UNITED STATES S., https://www.senate.gov/reference/glossary_term/appropriation.htm (last visited Mar. 20, 2018).

46. Andrew P. Han, *NAS Human Genome Editing Report Braces for Germline Modifications*, GENOMEWEB (Feb. 16, 2017) <https://www.genomeweb.com/gene-silencing-gene-editing/nas-human-genome-editing-report-braces-germline-modifications>.

47. *Id.*

national policy should favor caution.⁴⁸ The summit's organizing committee, which produced the policy stance of the summit, included biologists and bioethicists from a variety of countries.⁴⁹ The policy recommendations encourage preclinical research essential for curing disease but limited the use of clinical trials.⁵⁰

A. American Society of Human Genetics Statement

In reaction to the recent experiment in the United States, the American Society of Human Genetics (ASHG) issued a statement about germline editing research policy on August 3, 2017.⁵¹ ASHG advocated for restrictions that would not hinder the progress of safe experimentation.⁵² The statement recommended against "germline gene editing that culminate[d] in human pregnancy" due to the "nature and number of unanswered scientific, ethical, and policy questions."⁵³ ASHG also promoted publicly funding "research on the possible future clinical applications of gene editing."⁵⁴ The group advocated that such research could be done safely, using "in vitro germline genome editing on human embryos and gametes, with appropriate oversight and consent from donors."⁵⁵ But, before clinical research can proceed, there must be: "(a) a compelling medical rationale, (b) an evidence base that supports its clinical use, (c) an ethical justification, and (d) a transparent public process to solicit and incorporate stakeholder input."⁵⁶ Many groups from around the world endorsed the ASHG statement.⁵⁷

48. *Id.*

49. *See On Human Gene Editing: International Summit Statement*, NAT'L ACAD. OF SCI., ENG'G, & MED. (Dec. 3, 2015), <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a>.

50. *See id.*

51. *See generally* Ormond et al., *Human Germline Genome Editing*, 101 AM. J. HUM. GENETICS 167 (2017), <http://www.sciencedirect.com/science/article/pii/S0002929717302471?via%3Dihub> (indicating that representatives from the United Kingdom Association of Genetic Nurses and Counsellors, Canadian Association of Genetic Counsellors, International Genetic Epidemiology Society, and United States National Society of Genetic Counselors worked together with ASHG to formulate the statement).

52. *Id.* at 169.

53. *Id.* at 172.

54. *Id.* at 167.

55. *Id.* at 173.

56. Ormond et al., *supra* note 51.

57. Among them are "the American Society for Reproductive Medicine, Asia Pacific Society of Human Genetics, British Society for Genetic Medicine, Human Genetics Society of Australasia, Professional Society of Genetic Counselors in Asia, and Southern African Society for Human Genetics." *Id.*

The policy advocated by ASHG conflicts with Congress' current law prohibiting the use of federal funds for germline editing. As international and domestic groups increasingly support relaxed regulations, Congress will likely feel pressure to reconsider its stance on funding research. When considering how best to proceed, Congress is likely to look for inspiration among the states.⁵⁸

B. Development in the States: Different Perspectives

Many people, even within the United States, disagree over the best legal approach to germline editing. Some people, like Marcy Darnovsky, find moral problems with the practice and want a complete ban on germline editing research.⁵⁹ Many others, like R. Alta Charo, call for regulation, but not an outright prohibition on germline editing.⁶⁰ These different perspectives show up in state laws.⁶¹ Congress may consider the states as laboratories for democracy in this area. While germline editing is such a new field that few states have yet to specifically and directly address it, state laws regarding embryonic research provide insight to the activities scientists engage in for germline editing.

South Dakota is one of the few states with a current ban on any embryonic research that does not protect the life or health of the embryo.⁶² Under its state law, a human embryo includes single-cells living outside of the womb.⁶³ South Dakota prohibits any "nontherapeutic research that destroys a human embryo."⁶⁴ In another section, the law bans research that "subjects a

58. A discussion of other countries' policies and regulations is beyond the scope of this note.

59. Marcy Darnovsky, *Con: Do Not Open the Door to Editing Genes in Future Humans*, NAT'L GEOGRAPHIC, <http://www.nationalgeographic.com/magazine/2016/08/human-gene-editing-pro-con-opinions/> (last visited Sept. 4, 2018).

60. Pat Schneider, *UW's Alta Charo: Gene Editing for Inherited Human Traits 'Not Ready Now, Might be in Future'*, CAPITAL TIMES (Feb. 15, 2017), http://host.madison.com/ct/news/local/education/university/uw-s-alta-charo-gene-editing-for-inherited-human-traits/article_e478e29a-c2a2-59cd-83a4-03d2eb977fb6.html.

61. See 410 ILL. COMP. STAT. ANN. 110/1-50 (West 2008); MONT. CODE ANN. § 50-11-103 (West 2009); NEB. REV. STAT. ANN. §§ 28-346, 71-7606(3) (West 1979); S.D. CODIFIED LAWS §§ 34-14-16-17, 20 (2000).

62. *Embryonic and Fetal Research Laws*, NAT'L CONF. STATE LEGIS. (Jan. 1, 2016), <http://www.ncsl.org/research/health/embryonic-and-fetal-research-laws.aspx> (showing that germline editing at this early stage of research falls under this ban because the embryos die at the completion of research since the research is not yet ready for reproductive trials).

63. S.D. CODIFIED LAWS § 34-14-20 (2000).

64. *Id.* § 34-14-16.

human embryo to substantial risk of injury or death.”⁶⁵ Congress is not likely to use South Dakota as a model for legislation since Congress has never banned germline editing, despite recognizing the risks.⁶⁶

Nebraska takes a policy position similar to the federal government.⁶⁷ Nebraska permits embryonic research so long as the research subject is not an aborted live fetus.⁶⁸ Yet, the state prohibits the use of state funds from the Nebraska Health Care Funding Act for embryonic research.⁶⁹ Without any policy change, Congress will continue employing this type of regulatory scheme. But change is likely to occur after the recent experiment in the United States and policy recommendations by multiple scientific organizations. It appears increasingly likely that Congress will amend its regulatory scheme with each new advancement of science, making the possibility of health-based germline editing less risky.

Illinois is among the many states that not only allows embryonic research, but also provides public funding for the research.⁷⁰ In 2008, Illinois enacted a statute that permits funding for, and promotes research on, human embryonic germ cells.⁷¹ The state law favors embryonic research, providing that “[r]esearch involving the derivation and use of . . . human embryonic germ cells . . . shall be permitted and the ethical and medical implications of this research shall be given full consideration.”⁷² Further, the permitted research “shall be allowed to receive public funds through a program established specifically for the purpose of supporting stem cell research in Illinois under the Department of Public Health.”⁷³

Illinois recognized that the federal government was not providing funding in this area of great importance and innovation, so it developed a law that brings the advantages of embryonic research to Illinois. The purposes for creating the program are manifold.⁷⁴ First, the Illinois legislature wants “to improve the health of the citizens of Illinois through stem cell research.”⁷⁵ The legislature also wants “to support scientific research in Illinois for which funding from the U.S. government is currently restricted, namely human em-

65. *Id.* § 34-14-17.

66. *Id.* §§ 34-14-16–17, 20.

67. *Embryonic and Fetal Research Laws*, *supra* note 62.

68. NEB. REV. STAT. ANN. § 28-346 (West 1979).

69. *Id.* § 71-7606(3).

70. *Embryonic and Fetal Research Laws*, *supra* note 62.

71. 410 ILL. COMP. STAT. ANN. 110/1–/50 (West 2008).

72. *Id.* 110/5(1).

73. *Id.* 110/5(2).

74. *Id.* 110/15(b).

75. *Id.*

bryonic stem cell research.”⁷⁶ Further, the statute means “to improve the national competitive position of Illinois in the field of regenerative medicine.”⁷⁷ Finally, Illinois seeks “to promote the translation of stem cell research into clinical practice and the transfer of technology to biomedical and technological industry.”⁷⁸

The law of Illinois values progress and the health of its citizens over the risk of unknown certainty of using CRISPR.⁷⁹ This approach mirrors the recommendations of the recent ASHG statement.⁸⁰ The federal government also has an interest in remaining competitive “in the global bio-economy,” as shown from Congress’s change between the 2016 and 2017 appropriations bills.⁸¹ Therefore, Congress will likely soon take this inclusive path since the new approach balances those concerned with the ethics of designer babies and those who desire germline editing to cure crippling diseases. This path provides a happy medium that allows for research in a controlled, health-focused manner.

Montana falls within the diminishing minority of states that remains largely unregulated.⁸² The only mention to embryos addresses cloning.⁸³ A pertinent piece of the law, however, distinctly leaves the field open beyond cloning, stating that “[n]othing in this section prohibits embryonic stem cell research using embryonic stem cell lines of uncloned origin.”⁸⁴ Although it seems likely that Congress will decide to remove its prohibition of using public funds, bioethicists’ concerns prevent a complete deregulation from occurring in the near future. Further, people become accustomed to regulations, making it difficult to put the proverbial genie back in the bottle.⁸⁵ Both statements by prominent scientific organizations recommend against unrestrained germline editing and recognize that research is not yet ready to progress to

76. *Id.*

77. 410 ILL. COMP. STAT. ANN. 110/1–/50(b).

78. *Id.*

79. *See id.* 110/1–/50.

80. *See* Ormond et al., *supra* note 51.

81. *Compare* Consolidated Appropriations Act, 2017, 115 Pub. L. 31, Div. N, § 606, (May 5, 2017) <https://www.congress.gov/bill/115th-congress/house-bill/244> (including a directive to monitor how competitive the United States is in the global genetic editing field), *with* Consolidated Appropriations Act, 2016, 114 Pub. L. 113 (Dec. 18, 2015) (containing no similar directive to monitor).

82. *See Embryonic and Fetal Research Laws*, *supra* note 62.

83. MONT. CODE ANN. § 50-11-103 (West 2009).

84. *Id.* § 50-11-103(3).

85. *See* Sergio Hernandez, *Cutting Regulations is Not So Easy*, CNN (Jan. 31, 2017, 7:01 PM ET), <http://www.cnn.com/2017/01/31/politics/trump-regulations-executive-order/index.html>.

clinical trials.⁸⁶ Furthermore, the possibility that scientists will commercialize germline editing to produce designer babies and propagate eugenics seems to make deregulation impossible now that scientists in the United States are conducting germline editing experiments. Bioethicists and lawmakers are unlikely to allow scientists with the appropriate technology and monetary incentive to proceed without supervision.

Based on the large majority of states that allow public funding for embryonic research, Congress is likely to allow public funding for embryonic research. Outside influences this year from both the NAS International Summit and the ASHG internationally sponsored statement are encouraging Congress to keep its restrictions on reproductive clinical trials but allow funding on early-stage research.⁸⁷ Finally, the successful experiment in the United States this year shows that germline editing can become safer with increased research, which will lead to increased funding.⁸⁸

For those concerned about scientific overreach, Arthur Caplan, a bioethicist at New York University believes the scientific community can help solve the problem.⁸⁹ He proposes that eugenics can simply be avoided by line drawing.⁹⁰ He asserts that line drawing will be effective if “[s]cientists and bioethicists [] agree on rules on what should and should not be done, and then make sure that editors of scientific journals enforce them.”⁹¹ If scientists cannot get their research published, there will likely be less incentive to conduct impermissible research.⁹² In terms of Congressional restrictions, Caplan thinks funding should be available through a review committee that can permit funding for health-based research and refuse funding for designer baby experiments.⁹³ Ideally, safe and health-oriented research can be achieved if journals, private foundations, patient groups, and government work together.⁹⁴

IV. CONCLUSION

No matter what decision Congress makes in the near future, law in the area of germline editing will affect important aspects of American life. CRISPR can save lives and help families that suffer from reproductive and health problems, but it can also facilitate eugenics and create controversy

86. See Han, *supra* note 46; Ormond et al., *supra* note 51.

87. See Han, *supra* note 46; Ormond et al., *supra* note 51.

88. Connor, *supra* note 17.

89. Potenza, *supra* note 24.

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. See *id.*

over disabilities and class differences. Congress has many routes to influence its future treatment of germline editing, primarily the treatment of embryonic research by individual states. After weighing the value of the technology against the public policy concerns, Congress will likely start allowing public funds to be spent on safe, nonreproductive research in germline editing. But it will also reserve an assessment of clinical trials until after researchers know more about the risks and solutions. This choice of funding will encourage scientists to keep experimenting in the United States and promote healthy technological developments that will save lives.